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BY: Susan J. Kirst

DATE: July 1, 2002

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: Patent Application of : Group Art Unit 1634  
Susan J. Kirst, et al. :  
:   
Appln. No.: 09/596,194 : Examiner: Janell Taylor Cleveland  
:   
Filed: June 16, 2000 : Confirmation No.: 2288  
:   
For: NOVEL GENES ENCODING PROTEINS : Attorney Docket  
HAVING DIAGNOSTIC, PREVENTIVE : No. 10147-11U1  
THERAPEUTIC, AND OTHER USES : (MBIO99-054CP1)

**AMENDMENT  
AND  
REQUEST FOR RECONSIDERATION**

COPY OF PAPERS  
ORIGINALLY FILED

This paper is filed in response to the Office Action dated March 1, 2002 (Paper No. 11). This Amendment is timely filed by virtue of the accompanying Petition for a One-Month Extension of Time, which extends the period available for response through and including July 1, 2002.

Please amend the application as follows:

**In the Claims:**

Please amend claims 1, 18, 24, 25, 27, 29, 30, 32, and 34-38 as follows. For the Examiner's convenience, a "**Marked-Up Copy of Claims Amended**" is enclosed with this Amendment, wherein text added to the claims is underlined and text deleted from the claims is ~~struck through~~. Also enclosed is a "**Clean Copy of Claims, as Amended**" in which the claims, as amended to date, are listed in an order that the Applicants believe would be appropriate for issue.

Please amend claims 1, 18, 24, 25, 27, 29, 30, 32, and 34-38 to read as follows.

07/12/2002 NMOHAMM1 00000039 09596194

01 FC:103  
02 FC:102

396.00 OP  
168.00 OP

B1  
1. (Twice Amended) An isolated nucleic acid molecule selected from the group consisting of:

- a) a nucleic acid molecule having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules;
- b) a nucleic acid molecule comprising at least 400 nucleotide residues and having a nucleotide sequence identical to at least 400 consecutive nucleotide residues of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules;
- c) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules; and
- d) a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, wherein the fragment comprises at least 200 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules.

B2  
18. (Amended) A kit comprising a compound which selectively hybridizes with the nucleic acid molecule of claim 1 and instructions for use, wherein the compound comprises a polynucleotide that comprises at least 40 nucleotide residues and that hybridizes with the nucleic

B2  
acid molecule under stringent hybridization conditions, wherein the stringent hybridization conditions comprise hybridization in 6× sodium chloride/sodium citrate (SSC) at 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 65°C.

B3  
24. (Amended) The isolated nucleic acid molecule of claim 1, having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

25. (Amended) The isolated nucleic acid molecule of claim 24, having a nucleotide sequence which is at least 98% identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

B4  
27. (Amended) The isolated nucleic acid molecule of claim 24, having a nucleotide sequence identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

B5  
29. (Amended) The isolated nucleic acid molecule of claim 1, comprising at least 400 nucleotide residues and having a nucleotide sequence identical to at least 400 consecutive nucleotide residues of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

30. (Amended) The isolated nucleic acid molecule of claim 29, comprising at least 650 nucleotide residues and having a nucleotide sequence identical to at least 650

B5  
consecutive nucleotide residues of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

B4  
32. (Amended) The isolated nucleic acid molecule of claim 1, which encodes a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

B7  
34. (Amended) The isolated nucleic acid molecule of claim 1, which encodes a fragment of a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, wherein the fragment comprises at least 200 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules.

35. (Amended) The isolated nucleic acid molecule of claim 34, wherein the fragment comprises at least 647 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules.

36. (Amended) The isolated nucleic acid molecule of claim 34, wherein the fragment comprises at least 200 consecutive amino acid residues of SEQ ID NO: 61.

37. (Amended) An isolated nucleic acid molecule selected from the group consisting of:

a) a nucleic acid molecule having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules;

B7  
b) a nucleic acid molecule comprising at least 400 nucleotide residues and having a nucleotide sequence identical to at least 400 consecutive nucleotide residues of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules;

c) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules; and

d) a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, wherein the fragment comprises at least 200 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules,

wherein the nucleic acid molecule encodes a polypeptide that exhibits a biological function of TANGO 332 protein.

38. (Amended) The isolated nucleic acid molecule of claim 56, wherein the property is selected from the group consisting of iii) to ix) and wherein the human brain cells are glial cells.

Please add claims 41-59 as follows.

38  
- 41. The kit of claim 18, wherein the nucleic acid molecule has a nucleotide sequence which is identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of a cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

42. The kit of claim 18, wherein the nucleic acid molecule has a nucleotide sequence which is identical to the nucleotide sequence of SEQ ID NO: 59 or the complement thereof.

43. The isolated nucleic acid molecule of claim 37, having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

44. The isolated nucleic acid molecule of claim 37, comprising at least 400 nucleotide residues and having a nucleotide sequence identical to at least 400 consecutive nucleotide residues of any one of SEQ ID NO: 59, SEQ ID NO: 60, and the nucleotide sequence of the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

45. The isolated nucleic acid molecule of claim 37, which encodes a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, or the complement of any of these nucleic acid molecules.

46. The isolated nucleic acid molecule of claim 37, which encodes a fragment of a polypeptide comprising the amino acid sequence of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone deposited with ATCC® as Accession number PTA-151, wherein the fragment comprises at least 200 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules.

38  
47. An isolated nucleic acid molecule having a length of at least 2600 nucleotide residues, wherein the nucleic acid hybridizes under stringent hybridization conditions with a nucleic acid having the sequence SEQ ID NO: 60.

48. The isolated nucleic acid molecule of claim 47, wherein the stringent hybridization conditions comprise hybridization in 6× sodium chloride/sodium citrate (SSC) at about 45°C, followed by washing in 0.2× SSC, 0.1% SDS at 65°C.

49. The isolated nucleic acid molecule of claim 48, wherein the nucleic acid molecule encodes a polypeptide that exhibits a biological function of TANGO 332 protein.

50. The isolated nucleic acid molecule of claim 49, wherein the biological function is selected from the group consisting of

- i) ability to bind with hyaluronic acid;
- ii) ability to modulate human brain tissue organization;
- iii) ability to modulate interaction of human brain cells with brain extracellular matrix;
- iv) ability to modulate movement of human brain cells through brain extracellular matrix;
- v) ability to modulate growth of human brain cells;
- vi) ability to modulate proliferation of human brain cells;
- vii) ability to modulate differentiation of human brain cells;

- viii) ability to modulate adhesion between human brain cells; and
- ix) ability to modulate formation of neurological connections between human brain cells.

51. The isolated nucleic acid molecule of claim 47, wherein the molecule has a length of at least 2800 nucleotide residues.

Sub C1  
B8  
52. An isolated nucleic acid molecule having a sequence that encodes a protein that includes an amino acid sequence that is at least 70% identical to SEQ ID NO: 63 and exhibits a biological function of TANGO 332 protein.

53. The isolated nucleic acid molecule of claim 52, wherein the biological function is selected from the group consisting of

- i) ability to bind with hyaluronic acid;
- ii) ability to modulate human brain tissue organization;
- iii) ability to modulate interaction of human brain cells with brain extracellular matrix;
- iv) ability to modulate movement of human brain cells through brain extracellular matrix;
- v) ability to modulate growth of human brain cells;
- vi) ability to modulate proliferation of human brain cells;
- vii) ability to modulate differentiation of human brain cells;
- viii) ability to modulate adhesion between human brain cells; and
- ix) ability to modulate formation of neurological connections between human brain cells.

Sub C2  
54. The isolated nucleic acid molecule of claim 52, wherein the amino acid sequence is at least 95% identical to SEQ ID NO: 63.

55. The isolated nucleic acid molecule of claim 35, wherein the fragment comprises at least 649 consecutive amino acid residues of any one of SEQ ID NO: 61, SEQ ID



NO: 63, and the amino acid sequence encoded by the cDNA clone, or the complement of any of these nucleic acid molecules.

56. The isolated nucleic acid molecule of claim 37, wherein the biological function is selected from the group consisting of

- 38
- i) ability to bind with hyaluronic acid;
  - ii) ability to modulate human brain tissue organization;
  - iii) ability to modulate interaction of human brain cells with brain extracellular matrix;
  - iv) ability to modulate movement of human brain cells through brain extracellular matrix;
  - v) ability to modulate growth of human brain cells;
  - vi) ability to modulate proliferation of human brain cells;
  - vii) ability to modulate differentiation of human brain cells;
  - viii) ability to modulate adhesion between human brain cells; and
  - ix) ability to modulate formation of neurological connections between human brain cells.

57. An isolated nucleic acid molecule having a length of at least 300 nucleotide residues, wherein the nucleic acid hybridizes under stringent hybridization conditions with a nucleic acid having the sequence SEQ ID NO: 60.

58. The isolated nucleic acid molecule of claim 57, wherein the stringent hybridization conditions comprise hybridization in 6× sodium chloride/sodium citrate (SSC) at about 45°C, followed by washing in 0.2× SSC, 0.1% SDS at 65°C.

59. The isolated nucleic acid molecule of claim 58, wherein the nucleic acid molecule encodes a polypeptide that exhibits a biological function of TANGO 332 protein.

## REMARKS

Claims 1, 3-7, 16-18, and 24-59 are pending following entry of this Amendment. Claims 1, 18, 24, 25, 27, 29, 30, 32, and 34-38 have been amended. Claims 41-59 have been added. The amendments and additions made herein do not include new matter, as set forth in the ensuing section.

### Support in the Specification

In each of claims 1, 18, 24, 25, 27, 29, 30, 32, 34, 35, and 37, the terms, "*a complement thereof*" and "*its complement*" has been replaced with the synonymous term, "*the complement of any of these nucleic acid molecules.*" Because these terms are synonymous, the amended claims are supported by the originally filed claims.

The second incidence of the phrase "deposited with ATCC<sup>®</sup> as Accession number PTA-151" has been deleted from each of claims 1 (part d), 34, 35, and 37 (part d), because it is unnecessary. In addition, the phrase "its complement" has been deleted from each of these claims, as it refers to the deposited cDNA clone. The skilled artisan understands that it is immaterial whether a cDNA clone is deposited as a coding strand, a non-coding strand, or a double-stranded molecule, since either strand can be generated from the other or obtained from the double-stranded molecule. By removing these two phrases from each of these claims, the Applicants hope to avoid misunderstanding of the claims by others, and have not altered the meaning or scope of the claims.

In each of claims 1, 18, 24, 25, 27, 29, 30, 32, 34, 35, and 37, the phrase "... *a* cDNA clone deposited..." has been replaced with the phrase "... *the* cDNA clone deposited". cDNA clones were listed in the originally-filed claims as a Markush group (i.e., for which "a cDNA clone" was proper grammar). Now, only a single cDNA clone is listed, so the change is merely a grammatical correction.

In claim 18, a recitation has been added which further describes the compound which selectively hybridizes with the nucleic acid molecule recited in claim 1. Recitation that the compound is a polynucleotide that comprises at least 40 residues is supported in the specification, for example at page 3, lines 6-12. Recitation that the compound hybridizes under

the particularly-recited conditions is supported in the specification, for example at page 110, lines 14-17.

The length of the fragment recited in claim 35 was changed to 647 residues (TANGO 332 protein length of 671 residues, less the signal sequence of up to 24 residues; 672-24= 647; see the specification, for example at page 101, lines 1-9) in order to differentiate that claim from claim 34. Newly added claim 55 recites that the length of the identical portion of the fragment is at least 649 residues (as disclosed in the specification at page 95, lines 3-8).

Recitation of "a biological function of TANGO 332 protein" in claims 37, 49, 52, and 56 is supported in the specification, for example at page 101, lines 26 and 27.

In claim 36, SEQ ID NO: 61 (i.e., the sequence of immature TANGO 332, including the signal sequence) has simply been substituted in place of SEQ ID NO: 63 (i.e., the sequence of mature TANGO 332). Both sequences are described in the specification as TANGO 332 amino acid sequences.

Claim 38 was amended simply to adjust its dependency.

Newly added claims 47-51 and 57-59 claim the subject matter in an alternative manner, as disclosed in the specification, for example at page 110, lines 3-22.

Newly added claims 52-54 also claim the subject matter in an alternative manner, as disclosed in the specification, for example at page 111, lines 8-16.

Newly added claim 56 (which depends from claim 37) merely recites what was previously recited in claim 37.

For the foregoing reasons, the Applicants respectfully contend that the amendments and additions made herein do not include new matter.

### **Information Disclosure Statements**

The Office Action indicates that the Examiner returned to the Applicants' representative a copy of at least one Form PTO-1449 that had been forwarded to the Examiner. However, examination of the PTO-1449 enclosed with the Office Action reveals that the PTO-1449 was obtained from an un-related application. The Applicants have enclosed copies of the forms PTO-1449 filed with the Information Disclosure Statement (IDS) filed in this application

on 26 October 2000 and the Supplemental IDSs filed in this application on 30 October 2000 and 30 October 2001. Copies of the cited references were supplied with the three IDSs and are not enclosed with this Amendment. The Examiner is requested to consider each of the cited references and return the initialed forms PTO-1449 with the next communication.

#### **Correction of Inventorship**

A Request to Correct Inventorship Pursuant to 37 C.F.R. § 1.48(b) accompanies this Amendment, and requests that all inventors OTHER than Susan J. Kirst and Douglas A. Holzman be deleted from the application, in view of the claims remaining in this application.

#### **Objection to the Specification**

The Examiner objects to the specification on the grounds that certain information regarding the deposit referred to in the specification and claims is not disclosed. The Applicants direct the Examiner's attention to page 181, line 18, through page 182, line 25, at which the information to which the Examiner refers appears. The Applicants respectfully contend that this information satisfies the Examiner's objection, and that the objection should be withdrawn. Reconsideration and withdrawal of the objection to the specification are requested.

#### **Rejection of Claim 18 Pursuant to 35 U.S.C. § 112, First Paragraph**

In item 1 of the Office Action, the Examiner rejects claim 18. In the Examiner's view, the specification does not enable a skilled artisan to use any fragment of any size (e.g., 1, 2, 3, or hundreds of nucleotide residues) to selectively hybridize a nucleic acid molecule recited in claim 1. The Examiner appears to construe claim 18 to allow use of nucleic acid fragments of any size and to believe that the Applicants have not sufficiently described nucleic acids that will hybridize with a nucleic acid recited in claim 1. The Applicants have amended claim 18 in a manner that they believe alleviates the Examiner's concern. Claims 41 and 42 have also been added, each reciting a sub-set of what is recited in amended claim 18.

As amended, claim 18 recites that the compound which selectively hybridizes with the nucleic acid of claim 1 comprises a polynucleotide that hybridizes under specifically-

recited hybridization conditions (as disclosed in the specification, for example at page 110, lines 14-17). The Applicants respectfully contend that design of polynucleotide sequences that are sufficiently complementary to bind specifically with a known nucleotide sequence are well known in the art (e.g., design of a polynucleotide with a sequence complementary to 40 or more consecutive nucleotide residues of the known sequence). Methods of confirming that such polynucleotide-containing compounds specifically hybridize with the known sequence under the recited conditions are routine. For these reasons, the Applicants respectfully contend that the specification adequately enables the skilled artisan to make and use the compounds recited in amended claim 18.

The Examiner's citation of the Vas-Cath, Fiers, Amgen, Fiddes, and University of California cases in the rejection is believed to be inappropriate because the cases cited by the Examiner generally deal with situations in which molecules of unknown structure were claimed. In claim 18, the sequences of the nucleic acids with which hybridization is desired are known (i.e., SEQ ID NOs: 59 and 60 and the sequence deposited as PTA-151 are known). Generation of complementary sequences from these sequences is straight-forward. The skilled artisan recognizes that less-than-perfect complementarity will not eliminate hybridization, depending, for example, on the overall length and G-C content of the complementary regions. Therefore, the skilled artisan is able to predict (i.e., is put into possession of) the precise sequences of a wide variety of polynucleotides that will hybridize with the recited sequences. Furthermore, given a desired polynucleotide sequence, any of a variety of synthetic methods can be used to make the polynucleotide (i.e., the skilled artisan is enabled to make them), and any of a variety of hybridization methods can be used to hybridize the polynucleotides with their desired target (i.e., the skilled artisan is enabled to use them). For these reasons, the Applicants respectfully contend that they have adequately described and enabled the compounds recited in claim 18.

Reconsideration and withdrawal of the Examiner's rejection of claim 18 pursuant to 35 U.S.C. § 112, first paragraph, are respectfully requested.

### **Rejection of Claims 1, 3-7, 16-18, and 24-40 Pursuant to 35 U.S.C. § 112, First Paragraph**

Claims 1, 3-7, 16-18, and 24-40 stand rejected pursuant to 35 U.S.C. § 112, first paragraph. The Examiner's concern appears to be two-fold. First, the Examiner appears concerned that the claims include within their scope nucleic acids that are complementary to those explicitly recited, even if the degree of complementarity is less than 100%. Second, the Examiner appears concerned that some of the nucleic acid molecules recited in the claims do not encode proteins which exhibit an activity characteristic of TANGO 332 protein. The Applicants respectfully believe that both of these concerns are misplaced, and address the two issues separately in the two ensuing sub-sections.

#### **"Complements" of Nucleic Acids Recited in the Claims**

The Examiner suggests that the claims recite nucleotide sequences which are "complementary" to the nucleotide sequences that are explicitly recited in the claims, even if the degree of complementarity is less than 100%. However, this is not accurate. The claims explicitly recite nucleic acid molecules having certain nucleotide sequences and "a complement thereof" (see, for example, claim 1, parts a, b, and c) or "its complement" (see, for example, claim 1, part d). The Applicants believe that the Examiner has mistakenly considered one or both of these terms to refer to a nucleic acid molecule that has a sequence that can be complementary to only a portion of the recited nucleic acid (i.e., 1%, 10%, or 20% complementary). The Examiner suggests reciting in the claims that the complements referred to are "full" complements of the recited nucleic acid molecules. However, the Applicants believe that the terms used in the claims are synonymous with "full complement" and that the following explanation of the terminology clarifies the matter.

Every nucleic acid molecule has only one nucleotide sequence. Although many polynucleotides can be "complementary to" the nucleic acid molecule (i.e., polynucleotides having a region with a sequence complementary to at least a small portion of the nucleotide sequence), the nucleic acid molecule has only one "complement." The Examiner appears to refer to the complement as the "full complement;" however, this term is not standard in the art. The

Applicants respectfully contend that the term, "the complement" of a nucleic acid molecule is accepted in the art as having the definition proposed by the Examiner for "full complement."

In order to alleviate the Examiner's concern without altering the scope of the claims, the Applicants have amended the claims to eliminate use of "a complement thereof" and "its complement." In place of these terms, the Applicants have substituted "the complement of any of these nucleic acid molecules." The Applicants respectfully contend that these amendments clarify that the claims, as originally filed, included a recitation equivalent to the Examiner's suggested "full complement" recitation. Because the claims include a recitation equivalent to that suggested by the Examiner, the Applicants request that the Examiner not insist on inclusion of the non-standard term "full complement" in the claims.

#### Recitation of TANGO 332 Activity

In the rejection of claims 1, 3-7, 16-18, and 24-40 pursuant to 35 U.S.C. § 112, first paragraph, the Examiner appears concerned that some of the nucleic acid molecules recited in the claims do not encode proteins which exhibit an activity characteristic of TANGO 332 protein (see the Office Action, page 5, last full sentence, through page 6, first paragraph).

As an initial matter, the Applicants note that each of claims 37-40, (and newly added claims 43-46, 49-54, and 56) recites that the nucleic acid molecules within the scope of those claims exhibit a biological function of TANGO 332 protein (as disclosed in the specification, for example at page 99, line 6, through page 103, line 6), and that the Examiner's concern, on its face, should not apply to any of these claims.

Furthermore, while the Examiner's observation that the claims include nucleic acid molecules that do not encode a protein that exhibits a TANGO 332 activity within their scope is correct with respect to some claims, this is not a proper reason for rejecting the claims. The Examiner appears to assume that the nucleic acid molecules recited in the claims are useful only for encoding functional TANGO 332 protein. Although this use is among the uses for the claimed molecules, it is not the only use.

The claimed nucleic acid molecules are useful, for example, as probes or primers for detecting and/or amplifying polynucleotides that encode TANGO 332 (see specification,

page 2, lines 17-20). The claimed nucleic acid molecules are also useful, for example, in antisense methods of affecting TANGO 332 gene expression (see specification at page 112, line 15, through page 114, line 18). None of these uses requires that the claimed nucleic acid molecules encode functional TANGO 332 protein. Given the significance of the TANGO 332 activities disclosed in the specification (e.g., growth, proliferation, survival, differentiation, interaction, and activity of brain cells in humans afflicted with glioma, as disclosed in the specification at page 102, lines 1-14), the skilled artisan would understand the significant utility of nucleic acids for monitoring and modulating expression of TANGO 332. Thus, the skilled artisan would understand that useful TANGO 332 nucleic acids are not limited to those which encode active portions of TANGO 332 protein.

The Applicants respectfully contend that the nucleic acid molecules recited in the claims (i.e., throughout the full scope of those claims) have one or more of the uses disclosed in the specification, and that the Examiner should not require the Applicants to recite in the claims that the nucleic acid molecules encode functional TANGO 332 protein.

For the foregoing reasons, the Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 3-7, 16-18, and 24-40 pursuant to 35 U.S.C. § 112, first paragraph.

**Rejection of Claims 1, 3-7, 16-18, and 24-40 Pursuant to 35 U.S.C. § 112, Second Paragraph**

Claims 1, 3-7, 16-18, and 24-40 stand rejected in item 4 of the Office Action, pursuant to 35 U.S.C. § 112, second paragraph. In the Examiner's view, it is not clear what is included in the nucleic acid deposited with ATCC<sup>®</sup> as Accession Number PTA-151. The Applicants direct the Examiner's attention to page 181, line 18, to page 182, line 25, and to Table A on page 104 of the specification, where the contents, identity, and methods of extracting the deposit are disclosed. The Applicants respectfully contend that this information alleviates the Examiner's concern. Reconsideration and withdrawal of the Examiner's rejection of claims 1, 3-7, 16-18, and 24-40 pursuant to 35 U.S.C. § 112, second paragraph, are requested.



**Rejection of Claim 18 Pursuant to 35 U.S.C. § 112, Second Paragraph**

In item 5 of the Office Action, the Examiner rejects claim 18 pursuant to 35 U.S.C. § 112, second paragraph. In the Examiner's view, the contents of the instructions and the use to which the claimed kit is to be put are not clearly recited in the claims. The Examiner appears to recognize that the nucleic acid molecules recited in the claims have a variety of uses, and that the contents of the instructions depend on the use for which the kit is made. The Examiner exemplifies instructions suitable for a kit useful for detecting or amplifying all or part of a TANGO 332 gene in the Office Action. The Applicants respectfully contend that the skilled artisan is able to pair claimed nucleic acid molecules and appropriate instructions in the form of a kit, and that the Examiner's exemplification of this in the Office Action is evidence that skilled artisans can do so. In view of

- i) the variety of uses disclosed in the specification,
- ii) the ability of the skilled artisan to selected among the disclosed nucleic acid molecules to achieve those uses, and
- iii) the relatively high level of standardization of molecular biology methods for achieving the uses disclosed in the specification once the identity of the TANGO 332 gene became known,

the Applicants respectfully contend that the skilled artisan can prepare instructions for using the claimed nucleic acids once the nucleic acids and their intended uses are selected. For these reasons, the Applicants contend that the skilled artisan would understand what is included within the scope of claim 18, and that the claim is not indefinite.

Reconsideration and withdrawal of the Examiner's rejection of claim 18 pursuant to 35 U.S.C. § 112, second paragraph, are respectfully requested.

**Rejection of Claim 18 Pursuant to 35 U.S.C. § 102(b)**

In item 7, the Examiner rejects claim 18 pursuant to 35 U.S.C. § 102(b) in view of the Boehringer Mannheim catalog, which discloses a kit comprising a variety of hexanucleotides

having all possible hexanucleotide sequences. The Examiner contends that one or more of the hexanucleotides would selectively hybridize with a nucleic acid molecule recited in claim 1.

The Applicants have amended claim 18 such that it recites that the compound that selectively hybridizes with the nucleic acid molecule of claim 1 is a polynucleotide comprising at least 40 nucleotide residues. The hexanucleotides disclosed in the Boehringer Mannheim catalog clearly do not satisfy this recitation.

Reconsideration and withdrawal of the Examiner's rejection of claim 18 pursuant to 35 U.S.C. § 102(b) in view of the Boehringer Mannheim catalog are respectfully requested.

### Summary

The Applicants respectfully contend that each of pending claims 1, 3-7, 16-18, and 24-59 is in condition for allowance. Reconsideration and allowance of each of these claims are requested at the earliest possible time.

Respectfully submitted,

**SUSAN J. KIRST, ET AL.**

1 July 2002  
(Date)

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Enclosures: Petition for Extension of Time  
Marked-Up Copy of Amended Claims  
Clean Copy of Claims, as Amended  
Request to Correct Inventorship  
IDS and Form PTO-1449 filed by Applicants on 26 October 2000  
IDS and Form PTO-1449 filed by Applicants on 30 October 2000  
IDS and Form PTO-1449 filed by Applicants on 30 October 2001